Date: 12/8/99

Mr. Larry Spears
Food and Drug Administration
Office of Compliance
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Rockville MD 20850
FAX # (301) 594 - 4672

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RE: Sterility of Reprocessed Single Use Medical Devices

Dear Mr. Spears:

Recently, I learned that the FDA has proposed a new policy to regulate reprocessors of single use medical devices and will hold a "town meeting" on December 14th in Maryland to receive input on this new policy. Unfortunately, I am unable to attend the town meeting but I would like to submit my comments. Please accept this letter as my formal comment on the proposed new policy. While I strongly support the FDA's efforts to increase regulation of reprocessors of single use medical devices, I do not believe the new FDA policy is sufficient.

I am a GASTROENTEROLOGIST, and I work in SARASOTA MEMORIAL HOSP hospital in SARASOTA. I have been and continue to be concerned with the reuse of used disposable medical devices. I am concerned about the potential for patient injury from both a failure of the device as well as the spread of infectious diseases. These are not theoretical concerns. Published articles in *US News & World Report*, the *NY Times*, the *LA Times* and *Forbes Magazine* describe actual patient injuries. I also believe that many infections are under-reported due to insufficient patient tracking and that many injuries due to device failure are under-reported due to legal liability concerns.

Although many reprocessors claim that reprocessing has been going on for twenty years, the fact is that this was with respect to reusable devices and opened but unused single use devices. In today's cost cutting environment, it is proper to look at all possible areas to save money, but reprocessing complex, plastic, single used devices such as biopsy forceps, sphincterotomes, electrophysiology catheters and angioplasty catheters is simply not a safe avenue to pursue until these reprocessed devices receive FDA approval for reuse.

This practice also poses many ethical questions. There is no medical benefit to the patient, and, it is my understanding, that the patient does not receive lower healthcare costs. It is also my understanding that patients are not told that used disposable devices will be used on them. Without such knowledge, patients cannot protect themselves. As a healthcare professional, I want to speak out on their behalf.

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There can be no argument that if clinical tests were set up to prove whether or not a reprocessed used disposable device was safe for reuse, informed patient consent would be required. Strangely, proponents of reuse rely on a lack of any data to support a conclusion that reuse is safe and patients need not be told. Without sufficient data or approval from the FDA, the practice of reusing used disposable devices on patients is akin to human experimentation without patient consent.

I am thankful that the FDA is considering increased regulation of reprocessors, but, again, I do not believe the new policy is appropriate. The new policy would create new classifications of high, moderate and low risk devices. The existing regulations, however, already include a risk based classification scheme. The existing regulations also include regulations for reusable devices. Reprocessing a single use device simply renders it a reusable device. The new policy, therefore, is unnecessary.

The new policy is also insufficient to protect patient safety. Data proving safety and effectiveness will only be required for "high risk" devices, and FDA officials have stated publicly that very few devices will be deemed high risk. Reprocessors of low risk devices will receive even less regulatory oversight than they do today. As one example, many biopsy forceps are Class I exempt devices and will likely be deemed low risk devices, despite studies by manufacturers showing that many reprocessed biopsy forceps sitting on hospital shelves are contaminated with drug resistant bacteria. Importantly, biopsy forceps are critical devices which break the mucosal barrier when samples are taken and, thus, can easily pass bacteria remaining on the device to the unsuspecting patient. .

Reprocessors of single use devices claim to have the equipment and expertise necessary to "properly" reprocess used single use devices. They are, therefore, manufacturers in the eyes of healthcare workers and patients. In addition, reprocessing a single use device for reuse changes the device into a reusable device. Accordingly, reprocessors should be regulated in the same manner as original equipment manufacturers using the existing FDA regulations for reusable devices. To create a new regulatory policy wastes valuable FDA resources and delays regulatory enforcement putting, thus patients unnecessarily at risk for an undetermined period of time.

Sincerely,

Name: STEVE HARVEY
Title: